IS 11378 (2002): Anaesthetic Machines for Use with Humans [MHD 13: Veterinary Hospital Planning and Surgical Instruments]

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भारतीय मानक

मानवों के लिए प्रयुक्त निश्चेतक मशीनें

(पहला पुनरीक्षण)

Indian Standard

ANAESTHETIC MACHINES FOR USE WITH HUMANS

(First Revision)

ICS 11.040.10

BUREAU OF INDIAN STANDARDS
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Price Group 7

NATIONAL FOREWORD

This Indian Standard which is identical with ISO 5358 : 1992 'Anaesthetic machines for use with humans' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Anaesthetic, Resuscitation and Allied Equipment Sectional Committee (MHD 13) and approval of the Medical Equipment and Hospital Planning Division Council.

This standard IS 11378 was first published in 1985 as a dual number standard identical to ISO 5358 : 1980. Its first revision has been undertaken to incorporate the modifications effected in the second edition of ISO 5358 brought out in 1992. In this revision detailed requirements for gas mixers and a scheme for colour coding of vaporizers have been added. Separate clauses regarding information to be supplied by manufacturer and provision of user instruction manual have been introduced. Annexures giving test methods for cross-contamination, test methods for vaporizer accuracy with and without applied back pressure and method for filling vaporizer prior to testing for liquid discharge have been incorporated.

The text of ISO Standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appears referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

Indian Standard
ANAESTHETIC MACHINES FOR USE WITH HUMANS
(First Revision)

1 Scope

This International Standard specifies basic requirements for anaesthetic machines and associated components thereof for use with humans. It includes requirements for anaesthetic vaporizers intended for incorporation into anaesthetic machines covered by this International Standard.

The following are outside the scope of this International Standard:

a) anaesthetic machines which primarily depend on electric or electronic means for control or proper functioning;

b) intermittent-flow anaesthetic machines which only deliver gas to the breathing system at varying rates in response to the patient's inspiratory efforts;

c) dental nitrous oxide-oxygen analgesia machines.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content.*

ISO 407:1991, *Small medical gas cylinders — Pin-index yoke-type valve connections.*

ISO 3744:1981, *Acoustics — Determination of sound power levels of noise sources — Engineering methods for free-field conditions over a reflecting plane.*

ISO 4135:1979, *Anaesthesiology — Vocabulary.*

ISO 5356-1:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

ISO 5356-2:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors.*

ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems.*

ISO 7396:1987, *Non-flammable medical gas pipeline systems.*

ISO 7767:1988, *Oxygen analyzers for monitoring patient breathing mixtures — Safety requirements.*

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 4135 and the following definitions apply.

3.1 anaesthetic machine: Equipment for dispensing and delivering medical and anaesthetic gases and vapours into a breathing system.

3.2 gas mixer: Device which receives separate supplies of oxygen and other medical gas(es) and which delivers the mixed gases in concentrations adjustable by the operator.

3.3 machine gas piping: All pipework, including unions, from unidirectional valves in the pipeline inlets and from the outlets of the pressure regulators to the flow control system, as well as the piping connecting the flow control system and the piping connecting the vaporizers to the common gas outlet. It includes piping leading to and from pneumatic

alarm systems, gauges, oxygen flush and gas power outlets.

3.4 common gas outlet: That port through which the dispensed mixture from the anaesthetic apparatus is delivered to the breathing system.

3.5 flow control system: Device or assembly which controls and indicates the flow of gas.

3.6 flowmeter: Any device which indicates the volume of a specific gas passing through it in a unit of time.

3.7 pressure regulator: Gas pressure reducing and controlling device designed to provide a constant delivery (downstream) pressure over a range of variable inlet pressures and/or flows.

3.8 anaesthetic vaporizer: Device designed to facilitate the change of an anaesthetic agent from a liquid to a vapour.

3.9 vaporizer chamber: That part of a vaporizer where fresh gas becomes enriched or saturated with the vapour of the anaesthetic agent.

4 General

4.1 Anaesthetic machines should be designed to facilitate cleaning. All exposed surfaces should be able to withstand commonly used cleaning and disinfecting agents.

The suitability of materials should be assessed in respect of their compatibility with compressed oxygen and anaesthetic gases and vapours.

4.2 Anaesthetic machines shall comply with the following clauses of IEC 601-1:1988:

a) clause 22 — Moving parts;

b) clause 23 — Surfaces, corners and edges;

c) clause 24 — Stability in normal use;

d) clause 25 — Expelled parts;

e) clause 28 — Suspended masses.

4.3 All controls and gauges shall be clearly visible, and all gauges shall be legible, to an operator having visual acuity, corrected if necessary, of at least 1 seated or standing 1 m in front of the anaesthetic machine at an illuminance of 215 lx.

The markings and graduations should be readily identifiable with the controls, gauges, meters or other indicators with which they are associated. Flowmeters, gauges, controls and other displays that need to be read most frequently should be grouped together and should be placed as close as possible to the operator's field of vision when he/she is in the normal position for operating the anaesthetic machine and observing the patient.

4.4 Components which are intended to release anaesthetic gases or vapours during normal operation shall be provided with a means of collecting those gases for disposal via an anaesthetic gas scavenging system.

4.5 Except for vaporizers (see 13.2.11), if colour coding is used on the anaesthetic machine, it shall be in accordance with ISO 32, unless otherwise required by national regulations.

4.6 If the anaesthetic machine has built-in monitors, the monitors shall be enabled whenever the machine is enabled.

5 Medical gas cylinder connections

5.1 Medical gas cylinder connections shall be non-interchangeable between different gas services. All anaesthetic machines shall be provided with means of connection to a reserve oxygen supply.

5.2 Each cylinder connection or group of interconnected cylinder connections shall be provided with a filter having a pore size not exceeding 100 µm.

5.3 If medical gas cylinders have pin index yoke-type valve connections as specified in ISO 407, whether used as a service or reserve supply, they shall be connected to the anaesthetic machine by a corresponding pin indexed yoke.

If hanger yokes are provided, all yoke details, including the pin index safety system, shall be in accordance with ISO 407.

5.4 If two or more gas supply connections are provided for the same gas, means shall be provided to limit the leakage of gas to a flow not exceeding 100 ml/min, corrected to 20 °C and 101,3 kPa, from an open cylinder at a pressure of 15 MPa to any one of the following:

a) an empty cylinder;

b) through a cylinder connection to atmosphere;

c) a pipeline supply.

5.5 Each cylinder connection shall be permanently and legibly marked with the name or chemical symbol of the corresponding gas.

6 Pipeline inlet connections

6.1 If the anaesthetic machine is intended for use with a medical gas pipeline system, the oxygen and nitrous oxide gas systems shall each include pipeline hose inlets for connection to pipelines specified in ISO 7396. These inlets shall be the body (see figure 1) of the fittings specified either in ISO 5359 or in appropriate national standards. Such inlet connections shall be non-interchangeable and gas-specific.

6.2 Unidirectional valves shall be provided such that the reverse flow of gases from the anaesthetic machine to the pipelines or to atmosphere, if yokes for cylinders are also provided, shall not exceed 50 ml/min, corrected to 20 °C and 101,3 kPa, at the design working pressure(s) in the machine gas piping.

6.3 If pipeline inlet connections for gases other than nitrous oxide and oxygen (outlet connections for vacuum) are provided, they shall be gas-specific.

7 Pressure gauges, and pressure and contents indicators

7.1 General

NOTE 1 Pressure gauges cannot indicate the contents of cylinders containing liquefied gas.

7.1.1 Except for cyclopropane, each gas supplied at cylinder pressure to the anaesthetic machine shall be monitored by a cylinder pressure gauge or contents indicator. The scale of the gauge or indicator shall extend to a pressure at least 33 % greater than either the filling pressure of the cylinder or the full indication position at a temperature of 20 °C ± 3 °C.

7.1.2 If only one gauge is provided for a group of connections, it shall be possible to open the cylinder valves in any sequence so that the pressure in separate cylinders can be determined.

If more than one gas cylinder connection is supplied for any gas, one gauge or contents indicator should be provided for each connection.

7.1.3 Gases supplied by pipeline from central supplies shall be monitored by pressure gauges or indicators. These gauges or indicators shall monitor the pressure of gas in the pipeline supply hoses upstream of the unidirectional valve (see 6.2). If a gauge is used, it shall be capable of indicating a pressure not less than 33 % greater than the pipeline design working pressure.

7.1.4 All cylinder and pipeline pressure gauges shall be graduated in units of kPa × 100 and the units shall be clearly marked on the dial (see 4.3).

Additional markings and units of graduation may be used.

7.1.5 The maximum error of all gauges and indicators shall not exceed ± 4 % of the full scale reading.

7.1.6 If, in a single-fault condition, the pressure on the pressure-sensing element can be conveyed to the gauge case or enclosure, the gauge shall be designed and constructed in such a manner that when a pressure equal to the maximum pressure indicated on the dial or display is applied to a gauge having the pressure-sensing element removed, no parts shall be expelled free of the gauge enclosure. The cases of such gauges shall have a means of venting, to prevent a build-up of pressure within the case.

Gauges may be furnished with restrictors in the inlet pressure connection.

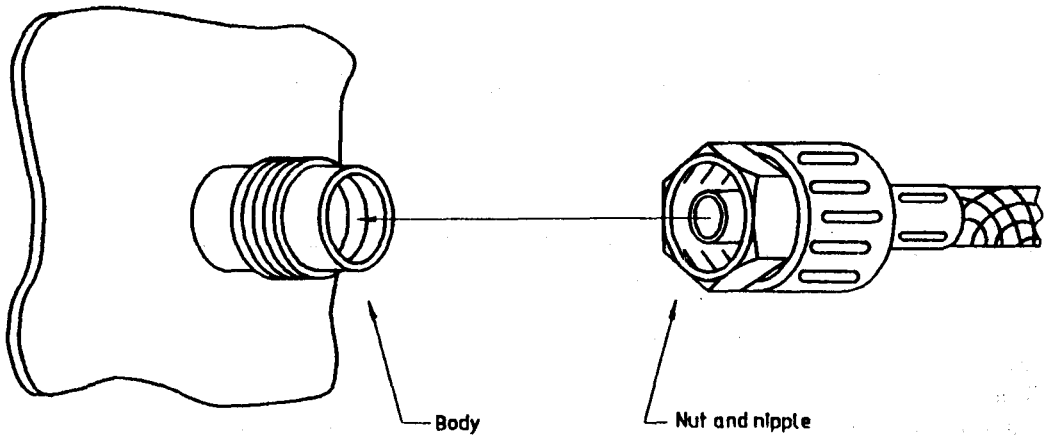

Figure 1 — Gas-specific connectors illustrating body and nut and nipple components

7.2 Gauges with analogue scales

7.2.1 All cylinder pressure gauges of a circular type on any individual anaesthetic machine shall have equal span angles to within ± 10°. The span angle, from the lowest pressure indication to the maximum pressure indication, shall be not less than 180° and not more than 300°, with the lowest pressure graduation mark at the same position between 6 o'clock and 9 o'clock on the dial.

7.2.2 The indicating end of the pointer shall be immediately apparent and shall contrast with the background. The pointer shall overlap but not obscure the scale marking. The tail end of the pointer shall be shorter than the indicating end and shall either blend with the background or be masked from view.

7.2.3 Analogue gauges shall have a scale length of not less than 50 mm and, if circular, shall be at least 38 mm in diameter. They shall be readily identifiable with the gas that they monitor.

8 Pressure regulators

8.1 There shall be an automatic pressure regulating system for each gas supplied to the anaesthetic machine from gas cylinder(s).

Each system may comprise either one automatic pressure regulator, or two or more automatic pressure regulators in series.

If the anaesthetic machine is connected to both the pipeline and a cylinder, the regulators should be set so that the anaesthetic machine uses the gas supply from the pipeline, when the pipeline is delivering at its rated value, in preference to other supplies that are connected to it.

8.2 With an indicated oxygen flow of 2 l/min, the time taken to restore the flow to 2 l/min ± 1 l/min after ten cycles of operating the oxygen flush for 10 s, with a pause of 5 s between flushes, shall not exceed 2 s.

8.3 A single regulator or the first regulator in a series shall be fitted with a relief valve that opens at not more than twice the nominal delivery pressure.

In a single-fault condition, the body of the pressure-regulating system shall maintain its integrity and the relief valve shall be capable of limiting the pressure in the system to not more than three times the nominal delivery pressure when the supply pressure is 50 % greater than the nominal maximum.

9 Machine gas piping

9.1 Machine gas piping shall withstand a pressure of at least twice its design working pressure without rupture.

9.2 Except for venting of air or oxygen from fluidic or pneumatic components, the leakage from that portion of the machine gas piping upstream of the flow control system shall not, at the design working pressure(s), exceed 25 ml/min corrected to 20 °C and 101,3 kPa for each gas service.

9.3 The leakage from that portion of the machine gas piping between the flow control system and the common gas outlet shall not, at a pressure of 3 kPa, exceed 50 ml/min corrected to 20 °C and 101,3 kPa for each gas service. This requirement shall be met under the following conditions:

a) with the vaporizer on;

b) with the vaporizer off;

c) if the anaesthetic machine is fitted with a user-detachable vaporizer, with the vaporizer removed.

9.4 Except where the connectors of gas piping are non-interchangeable, anaesthetic machine pipework shall be labelled at each junction, and where the piping joins a component, with the name, chemical symbol or other coding of the gas.

9.5 Gas system components, either separately or in combination, shall be compatible with the appropriate gas under the conditions of containment and use.

10 Flow control system

10.1 A flow control system shall be provided for each gas. To prevent incorrect adjustment of the flow of a single gas, there shall be only one flow adjustment control for each gas delivered to the common gas outlet.

NOTE 2 Devices to prevent hypoxic mixtures whereby oxygen is made to flow with other gas(es) are not considered to be flow adjustment controls.

10.2 Each flow control system shall maintain any flow within its graduated range to within ± 10 % of setting or ± 30 ml/min, whichever is the greater, for 10 min when the supply pressure and the pressure at the common gas outlet are varied within the range of pressures stated by the manufacturer.

10.3 Rotary flow adjustment controls shall continuously increase the gas flow when turned in an anti-clockwise direction and continuously decrease the gas flow when turned in a clockwise direction.

10.4 When the common gas outlet is venting to atmosphere, each rotary flow adjustment control, except those for carbon dioxide and cyclopropane, shall require rotation through at least 180° to adjust its associated flowmeter or flow indicator through the upper 90 % of the scale range.

10.5 The leakage through a rotary flow adjustment control or other device intended to shut off gas shall not exceed 5 ml/min at the design pressure.

NOTES

3 An increasing number of anaesthetic machines are being designed whereby the oxygen and nitrous oxide controls interact to prevent the oxygen concentration falling below 25 % (V/V) when these two gases only are in use.

4 Some anaesthetic machines may incorporate a minimum pre-set flow of oxygen.

10.6 Each flow adjustment control shall be adjacent to or readily identifiable with the flowmeter or flow indicator that it controls.

10.7 The flow adjustment control or its surroundings shall be permanently and legibly marked with the name or chemical symbol of the gas which it controls.

10.8 The stem of each rotary flow adjustment control shall be captive such that it cannot be disengaged from its housing without the use of tools.

10.9 For rotary flow adjustment controls, the oxygen control knob shall have a physically distinguishable profile in accordance with figure 2. All other flow adjustment control knobs shall be round.

NOTE 5 The oxygen control knob may be arranged to project beyond the knobs controlling other gases when they are grouped.

The diameter of the oxygen control knob shall be not less than the diameter of the knobs controlling other gases. The surface finish serrations of these other knobs shall have a depth not exceeding 1 mm.

10.10 If the flow control system uses threaded needle valves, when axial push and pull forces of 10 N $\pm$ 2 N are applied to the spindle of each valve, without rotation, with the flow at 25 % of maximum indicated flow, any change in flow shall not exceed 10 % or 10 ml/min, whichever is the greater.

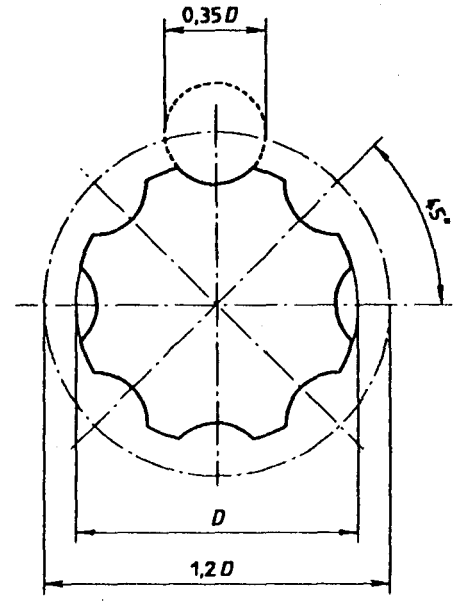

Figure 2 — Profile of oxygen flow control knob for applications other than vaporizer flow control

11 Flowmeters

11.1 The requirements given in this clause apply to flowmeters for single or pre-mixed gases.

Measures should be taken to minimize the build-up of electrostatic charges both inside and outside the tubes and housings of tube-type flowmeters.

NOTE 6 An anaesthetic machine may be equipped with one or more flowmeters for each gas supplied. (See also 10.1 and NOTE 2.)

11.2 Each flowmeter shall be calibrated for discharge into an ambient atmosphere of 101,3 kPa at an operating temperature of 20 °C.

All flowmeters shall be graduated in units of litres per minute. For flows of less than 1 l/min, the flow shall be expressed either in millilitres per minute or in decimal fractions of a litre per minute, with a zero before the decimal point. For flows of 1 l/min and above, sub-divisions of a litre shall be expressed in decimal parts. The method of graduation of all flowmeters on the anaesthetic machine shall be the same.

If tube-type flowmeters are used, the flowmeter scale shall be either marked on the flowmeter tube, or, if separate, shall be on the right-hand side of the tube as viewed from the front. In all cases, the name(s) or chemical symbol(s) of the gas or gas mixture shall be marked on the flowmeter. The scale markings shall be visible when viewed through an

arc of 45° both to the right and the left of a centre line perpendicular to the scale markings.

Flowmeters of the tube type should be designed so that the scale, tube and float are clearly associated.

The manufacturer should ensure that the flowmeter tubes are not interchangeable by the user between different gas flowmeter locations or between different locations of the same gas.

11.3 The accuracy of the graduations of any flowmeter used on an anaesthetic machine shall be within 10 % of the indicated value for flows between 10 % of full scale or 300 ml/min, whichever is the greater, and 100 % of full scale when discharged into an ambient atmosphere of 101,3 kPa at an operating temperature of 20 °C.

11.4 If oxygen and other gases are delivered by their respective flowmeters into a common manifold, the oxygen shall be delivered downstream of all other gases.

11.5 If a bank of flowmeters is fitted, the oxygen flowmeter shall be placed at one extremity.

11.6 Flowmeter floats shall be visible to the operator at all settings (see also 4.3).

11.7 The point of reference for reading the float shall be marked on the flowmeter assembly.

12 Gas mixers

12.1 If a gas mixer is fitted to or integral with an anaesthetic machine, it shall meet the requirements given in 12.2 to 12.6 and, except for air/oxygen mixers, shall not deliver an oxygen concentration of less than 25 % (*V*/*V*).

12.2 The set concentration of oxygen (% *V*/*V*) in the delivered gas shall be marked or indicated on or adjacent to the gas mixture control.

12.3 If fitted, flowmeter(s) controlling gas supplied to a gas mixer shall comply with 11.3. Any flow control system fitted to a gas mixer shall comply with 10.2.

If a gas mixer is used in addition to, or instead of, independent flow control of different gases, there shall be an indication of the gases controlled, the concentration of oxygen in the mixture and the total fresh gas flow or delivered minute volume.

NOTE 7 The accuracy of flowmeter(s) fitted to the output side of a gas mixer which indicate(s) total flow is dependent upon the composition of the delivered gas [see clause 19 h)].

12.4 At any flow and inlet pressure within the range given in the user instruction manual, the delivered oxygen concentration shall be within ± 5 % (*V*/*V*) of the indicated value.

12.5 The names or chemical symbols of the gases that the gas mixer controls shall be marked or indicated on or adjacent to the gas mixer control.

12.6 When an anaesthetic machine to which a gas mixer is fitted is tested as described in annex A, the flow of gas from one gas inlet to the other gas inlet shall not exceed 5 ml/min.

13 Vaporizers

13.1 General

13.1.1 Provision shall be made on the anaesthetic machine for the fitting of one or more vaporizers between the flowmeter/gas mixer manifold outlet and the oxygen flush connection (see clause 16).

13.1.2 If conical connectors are used at the vaporizer inlet and outlet, they shall be of 23 mm size in accordance with ISO 5356-1. The connector at the inlet shall be male and that at the outlet shall be female. Any other system of connectors for vaporizers shall ensure that the vaporizer can only be fitted so that gas flow through it is in the intended direction.

13.1.3 The direction of gas flow through the vaporizer(s) shall be marked with an arrow(s).

13.2 Concentration-calibrated vaporizers

13.2.1 Concentration-calibrated vaporizers produce controllable partial pressures of anaesthetic vapours which are independent of ambient pressure. By convention, vaporizers are calibrated in % (*V*/*V*) at a standard atmosphere of 101,3 kPa at a temperature of 20 °C ± 3 °C.

13.2.2 Concentration-calibrated vaporizers shall accept a gas flow of at least 15 l/min and deliver the gas with a controllable concentration of vapour.

13.2.3 A control to adjust the vapour concentration shall be provided. A scale or display shall be provided for the calibrated range of the vaporizer. It shall not be possible to set the control above the calibrated range.

13.2.4 To prevent contamination of the contents of one vaporizer with another agent, means shall be provided to prevent gas passing through the vaporizing chamber of one vaporizer and then of another.

13.2.5 The vaporizer shall have a visual liquid level indicator to indicate the maximum and minimum levels in the agent reservoir.

13.2.6 Rotary dials/knobs on the vaporizer shall increase the delivered concentration of vapour when turned anti-clockwise. There shall be a detent for the "off" position or for the "zero" position if this is also the "off" position.

13.2.7 When tested as described in annex B using the carrier gas and analytical technique recommended by the manufacturer [see clause 19 m) 4)], the following requirements shall be met.

a) The delivered concentration shall not exceed 0,1 % (*V*/*V*),

   1) when the vaporizer control is in the "zero" position, if provided;

   2) when the vaporizer control is in the "off" position, if provided; or

   3) when the vaporizer control is in either the "zero" or "off" position, if both positions are provided.

b) The delivered concentration at all graduations other than "off" or "zero" shall not deviate from the indicated value by more than ± 20 % of the concentration setting or ± 5 % of the maximum graduation, whichever is the greater.

13.2.8 When tested as described in annex C using the carrier gas and analytical technique recommended by the manufacturer [see clause 19 m) 4)], the delivered concentration from the vaporizer shall not vary by more than + 30 %/− 20 % from the concentration setting or + 7,5 %/− 5 % of the maximum graduation, whichever is the greater.

13.2.9 When the vaporizer has been filled, as described in annex D, to the maximum filling level and when the vaporizer control is set to both the "off" and maximum control setting, no liquid shall be discharged from the vaporizer with a flow of 20 l/min passing through it.

13.2.10 A label shall be attached to the vaporizer or the anaesthetic machine which either states the words "Before using this vaporizer, read the instruction manual" or bears the symbol given below.

13.2.11 The vaporizer shall be marked with the generic name of the anaesthetic agent for which it is calibrated. If colour coding is used, the colours shall be as named in the second column of table 1.

Table 1 — Colours for colour coding of vaporizers

Anaesthetic agent	Specified colour[1)]	Examples of suitable colour samples[1)]					
		USA Federal Standard 595a	BS 5252	Pantone	SS 01 91 00-SS 01 91 03	Munsell	DIN 6164
Halothane	Red	11105	04 E 56	200	1374/R	5R4/14	8:7:2
Enflurane	Orange	22510	06 E 55	144	0958-Y56R	2.5YR 6/16	5:5:1
Methoxyflurane	Green	14187	14 E 53	334	2356-B92G	10G 5/10	21:6:3
Trichloroethylene	Blue	15102	20 E 56	294	4052-R92B	2.5PB 3/8	17:7:4
Sevoflurane	Yellow	13655	10 E 53	115	1070-Y10R	5Y 8/14	2:6:1
Isoflurane	Purple	None	24 E 53	252/253	3248-R42B	7.5P4/12	11:4:4

1) Column 2 gives the specified colour. Columns 3 to 8 give examples of suitable colour samples extracted from commonly used national or other standards (see annex E).

14 Common gas outlet

14.1 The common gas outlet shall be a coaxial 22 mm male/15 mm female conical connector complying with ISO 5356-1 or ISO 5356-2. The axis of the common gas outlet shall be within ± 10° of the horizontal.

14.2 For conical connectors, the supporting structure of the common gas outlet shall permit the simultaneous application of a bending moment of 3 N·m on, and a torque of 3 N·m around, the axis without permanent deformation or displacement of the mountings of the common gas outlet.

14.3 If the common gas outlet includes a screw-threaded weight-bearing connector in accordance with ISO 5356-2, its supporting structure shall permit the simultaneous application of a bending moment of 10 N·m on, and a torque of 24 N·m around, the axis without permanent deformation or displacement of the mountings of the common gas outlet.

15 Gas power outlets

15.1 Gas power outlets, if fitted, shall be for air and/or oxygen only and shall be the body of a gas-specific connector complying with either ISO 5359 or the appropriate national standard.

15.2 Gas power outlet connectors shall be self-sealing to comply with 9.2.

16 Oxygen flush

16.1 The anaesthetic machine shall be fitted with a manually operated single-purpose oxygen flush for the delivery of a limited but unmetered flow of oxygen directly to the common gas outlet. A flush shall not be provided for any other gas.

16.2 The oxygen flush control shall have only one "off" position.

The oxygen flush control should be designed and sited to minimize accidental operation by equipment or personnel pressing against it.

16.3 The oxygen flush control shall be operable with one hand and shall be self-closing.

16.4 The flush shall deliver oxygen from the common gas outlet to atmosphere at a steady flow of between 35 l/min and 75 l/min, measured at atmospheric pressure, when oxygen is delivered to the flush at its design working pressure.

16.5 The flow of gas from the oxygen flush shall be delivered to the common gas outlet without passing through a vaporizer. When the common gas outlet is open to atmosphere, the pressure at the outlet from the vaporizer shall not increase by more than 10 kPa above its normal working pressure when the oxygen flush is operated.

16.6 The oxygen flush control shall be clearly marked (see 4.3) with one of the following:

a) "oxygen flush";

b) "O_2 flush";

c) "O_2+".

17 Oxygen supply failure

17.1 Oxygen supply failure alarm [see also clause 19 f)]

17.1.1 The anaesthetic machine shall have an auditory alarm to indicate failure of the oxygen supply, whether that supply is derived from cylinders or from a pipeline system. This auditory alarm shall be either gas- or electrically-powered.

17.1.2 The auditory alarm shall be of at least 7 s duration and, when tested as described in ISO 3744, its A-weighted sound pressure level shall be at least 2 dB above a background white noise of 55 dB.

17.1.3 It shall not be possible to shut off or reset the alarm without first restoring the oxygen supply pressure to above the alarm point.

17.1.4 If the alarm is gas-powered, the energy required to operate it shall be derived from the oxygen supply pressure in the machine gas piping between the cylinder or pipeline inlet and the oxygen flowmeter control.

17.1.5 Electrically-powered alarms shall be operative in the case of electrical power failure, except when an electrical power failure alarm is fitted. Means shall be provided for testing the alarm system.

17.1.6 If a visual alarm is also incorporated, it shall be a red signal, a red light or an alpha-numeric display, which shall be activated together with the auditory alarm and, if a red signal or red light is used, shall be labelled. This alarm shall be automatically deactivated when the oxygen supply is restored.

17.2 Cut-off devices for gases other than oxygen (oxygen pressure failure protection device)

17.2.1 The anaesthetic machine shall be fitted with a gas cut-off which shall be activated as specified in the user instruction manual and shall perform one of the following functions:

a) cut off the supply of all gases other than oxygen to the common gas outlet;

b) cut off the supply of all gases other than oxygen and air to the common gas outlet;

c) progressively reduce the flow of all other gases while maintaining the pre-set oxygen flow or proportion of oxygen until the supply of oxygen finally fails, at which point the supply of all other gases shall be shut off;

d) progressively reduce the flow of all other gases, except air, while maintaining the pre-set oxygen flow or proportion of oxygen until the supply of oxygen fails, at which point the supply of all other gases, except air, shall be shut off.

NOTE 8 The gas cut-off device may also open the breathing system to atmosphere.

17.2.2 The gas cut-off device shall not cut off completely the supply pressure of any gas before the oxygen failure alarm is activated.

17.2.3 The sole means of resetting the gas cut-off device shall be the restoration of the oxygen supply pressure to a level above that at which the device is activated.

17.3 Oxygen analyzers

If an anaesthetic machine is fitted with an oxygen analyzer, it shall comply with ISO 7767.

18 Information to be supplied by manufacturer

The manufacturer shall supply details of the operational checks to be carried out before using the anaesthetic machine and these shall be located on the machine.

19 User instruction manual

A user instruction manual, or manuals, shall be supplied with each anaesthetic machine and shall include the following information:

a) recommended methods for sterilization or disinfection of the anaesthetic machine and its components;

b) instructions for testing for correct assembly and connection of each gas supply system and any vaporizers fitted to the machine;

c) details of any relief valves fitted to the machine;

d) details of the accuracy of the flowmeter graduations at flows below 300 ml/min;

e) the pressure and flow characteristics of any gas power outlet under stated pipeline inlet and test conditions;

f) full details of the oxygen failure alarm system(s) and the associated cut-off devices;

g) test method(s) for function of the alarm(s);

h) if the anaesthetic machine is fitted with a gas mixer(s), the leakage from one gas inlet to the other, including the design pressure(s) and pressure differential, the recommended range of flows from the mixer(s) and the accuracy, for the range of compositions of the delivered gas, of flowmeters fitted to the output side of gas mixers;

i) the service interval recommended by the manufacturer;

j) lung ventilators recommended for use with the anaesthetic machine, if appropriate;

k) breathing systems recommended for use with the anaesthetic machine;

l) the words "an oxygen analyzer complying with ISO 7767 must be used when the anaesthetic machine is used";

m) if the anaesthetic machine is fitted with a vaporizer(s) by the manufacturer or it is intended that a recommended vaporizer(s) is to be fitted according to his instructions, the following:

   1) details of the vaporizer's performance, including the effects of variation in ambient temperature, ambient pressure, tilting, back pressure, input flow up to 15 l/min or for the range stated by the manufacturer, whichever is the greater, and gas mixture composition;

   2) a warning that the performance of the anaesthetic machine and vaporizer may be degraded if the two are mis-matched;

   3) if the vaporizer is fitted with an agent-specific filling device, instructions for its use;

4) the carrier gas, gas flow(s) and analytical technique recommended for testing the vaporizer and, if the anaesthetic machine is recommended for use with a ventilator, the ventilator settings to be used when testing the vaporizer;

5) a statement of why the vaporizer should not be used with its control set between "off" and the first graduation above zero, if the vaporizer cannot be calibrated in this range;

6) the volume of anaesthetic agent required to fill the vaporizer from the minimum filling level to the maximum filling level.

Annex A
(normative)

Test method for cross-contamination

A.1 Set up the gas mixer as shown in figure A.1 and determine the cross-contamination from gas source 1 to gas source 2 as described in A.2 to A.8.

A.2 Set the gas mixture control to 50 % and set the flow from the mixer to zero.

A.3 Determine to within ± 10 % the internal volume, V_1, in litres, of the pipeline and passages within the mixer relating to gas source 2 up to isolation valve 2. This volume should be approximately 300 ml.

A.4 Set the gas sources to their design operating pressures and record the pressure of gas source 1, p_1, in kilopascals.

A.5 Close isolation valve 2.

A.6 Open bleed valve 2 and allow the pressure to drop by 35 kPa. Close bleed valve 2 and allow the pressure to stabilize for 10 s. Record this pressure, p_2, in kilopascals.

A.7 Start a stopwatch and after 2,5 min, t_1, record the pressure reached on pressure gauge 2, p_3, in kilopascals, ensuring that p_1 remains constant.

A.8 Calculate the cross-contamination C, in millilitres per minute, from gas source 1 to gas source 2 from the following equation:

$$C = \left(\frac{V_1 (p_3 - p_2)}{t_1 \times p_1} \right) 1\,000$$

where the symbols are as given in A.3 to A.7.

A.9 Carry out the procedure described in A.1 to A.8 to determine the cross-contamination from gas source 2 to gas source 1.

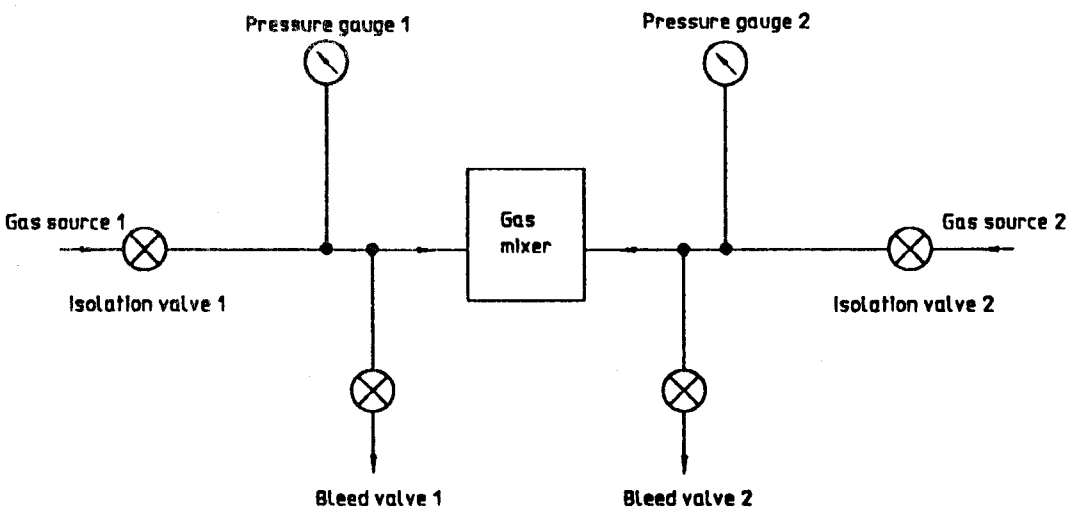

Figure A.1 — Test apparatus for determining cross-contamination

Annex B
(normative)

Test method for vaporizer accuracy without applied back pressure

B.1 General

B.1.1 Test the anaesthetic machine with the vaporizer, breathing system and, if applicable, lung ventilator recommended by the manufacturer or supplier (see clause 19). Carry out preliminary checks to ensure that components downstream of the vaporizer will not affect the test results, for example by absorbing volatile anaesthetics or imposing time delays on response or by leakage.

B.1.2 Use the carrier gas and analytical technique recommended by the manufacturer [see clause 19 m) 4)].

The accuracy of the analytical technique should be within ± 10 % of the tolerance specified in 13.2.7.

B.2 Procedure

B.2.1 Fit the empty vaporizer in position on the anaesthetic machine.

B.2.2 Place the anaesthetic machine and anaesthetic agent in the test room for at least 3 h at a temperature of 20 °C ± 3 °C and maintain this temperature throughout the test procedure.

B.2.3 Fill the vaporizer with the appropriate anaesthetic agent to the minimum mark on the liquid level indicator, add a further 10 ml ± 1 ml of agent and leave the vaporizer to stand for at least 45 min.

This may be within the 3 h period specified in B.2.2.

B.2.4 Set the vaporizer to the "on" position at the maximum concentration setting. Purge the vaporizer for 3 min at a flow of 2 l/min.

B.2.5 Connect a vapour analyzer to the common gas outlet of the anaesthetic machine or, if applicable, to the inspiratory port of the lung ventilator. With the vaporizer in the "off" position, set the gas flow through the anaesthetic machine to 2 l/min ± 0,2 l/min and adjust the ventilator, if applicable, to give 15 breaths/min ± 2 breaths/min at an I:E ratio of 1:2 ± 20 % with the inspiratory flow control set to maximum. Ensure that any pressure fluctuation at the common gas outlet is within the range − 0,5 kPa to + 0,5 kPa.

For an anaesthetic machine in which the fresh gas flow is determined by the ventilator settings, set these to give a minute volume of 2 l/min ± 0,2 l/min. Maintain the gas flow for 1 min and measure the concentration of vapour.

B.2.6 Repeat the procedure described in B.2.5 with the vaporizer set to each of its other settings in the order given in table B.1. If the vaporizer is not marked with those concentration settings given in table B.1, use the nearest settings on the vaporizer. If any setting given in table B.1 is equidistant between settings on the vaporizer, use the lower setting on the vaporizer.

B.2.7 Repeat the sequence of measurements described in B.2.5 and B.2.6 but using a fresh gas flow of 8 l/min ± 0,8 l/min.

For an anaesthetic machine in which the fresh gas flow is determined by the ventilator settings, set these to give a minute volume of 8 l/min ± 0,8 l/min.

B.2.8 Repeat the sequence of measurements given in B.2.6 using a gas flow and, if applicable, ventilator settings recommended by the manufacturer for testing the vaporizer [see clause 19 m) 4)].

Table B.1 — Settings to be used for testing vaporizer accuracy

Order of test	Setting (% *V*/*V* of anaesthetic agent) [1]
1	off, and zero if separately marked
2	lowest graduation above zero
3	0,5
4	1
5	2
6	4
...	...
last	maximum graduation (full scale)

1) If 0,5 % is the lowest graduation, step 2 is omitted.

Annex C
(normative)

Test method for vaporizer accuracy with applied back pressure

C.1 General

C.1.1 Test the anaesthetic machine with the vaporizer, breathing system and, if applicable, lung ventilator recommended by the manufacturer or supplier (see clause 19).

C.1.2 Use the analytical technique recommended by the manufacturer [see clause 19 m) 4)].

The accuracy of the analytical technique should be within ± 10 % of the tolerance specified in 13.2.8.

C.2 Procedure

C.2.1 Fit the vaporizer in position on the anaesthetic machine and drain the vaporizer.

C.2.2 Place the anaesthetic machine and anaesthetic agent in the test room for at least 3 h at a temperature of 20 °C ± 3 °C and maintain this temperature throughout the test procedure.

C.2.3 Fill the vaporizer with the appropriate anaesthetic agent to the minimum mark on the liquid level indicator, add a further 10 ml ± 1 ml of agent and leave the vaporizer to stand for at least 45 min.

C.2.4 Set the vaporizer to the "on" position at the maximum concentration setting. Purge the vaporizer for 3 min at a flow of 2 l/min.

This may be within the 3 h period specified in C.2.2.

C.2.5 Connect a vapour analyzer to the common gas outlet of the anaesthetic machine or, if applicable, to the inspiratory port of the lung ventilator. With the vaporizer in the "off" position, set the gas flow through the anaesthetic machine to 2 l/min ± 0,2 l/min and adjust the ventilator to give 15 breaths/min ± 2 breaths/min at an I:E ratio of 1:2 ± 20 % with the inspiratory flow control set to maximum.

C.2.6 Introduce a pressure fluctuation at the common gas outlet of 2 kPa ± 0,3 kPa.

This can be achieved by using a test lung having a compliance of 200 ml/kPa and a variable resistance.

Ensure that the decay time during the expiration period from 100 % of the pressure at the end of the inspiration period to 33 % of this pressure is less than 0,6 s.

For an anaesthetic machine in which the fresh gas flow is determined by the ventilator settings, set these to give a minute volume of 2 l/min ± 0,2 l/min.

C.2.7 Set the vaporizer to deliver either 20 % of its maximum concentration setting or its minimum concentration if this is greater than 20 % of its maximum setting. If the vaporizer is not marked with this concentration, use the nearest setting and if the required setting is equidistant between two settings, use the lower one.

Maintain the pressure fluctuation for 3 min and measure the concentration of anaesthetic agent delivered over a further 1 min period while maintaining the pressure fluctuation. Calculate the average vapour concentration in the total delivered gas flow.

C.2.8 Repeat the procedure using a fresh gas flow of 8 l/min ± 0,8 l/min and a pressure fluctuation at the common gas outlet of 5 kPa ± 0,4 kPa.

For an anaesthetic machine in which the fresh gas flow is determined by the ventilator settings, set these to give a minute volume of 8 l/min ± 0,8 l/min.

Annex D
(normative)

Method of filling vaporizer prior to testing for liquid discharge

D.1 General

Test the vaporizer when fitted to the anaesthetic machine. Half fill the vaporizer with anaesthetic agent, as described in the user instruction manual, wait for 5 min and then proceed using one of the methods described in D.2 and D.3.

D.2 Fillers into which anaesthetic agent is poured directly from a bottle

D.2.1 Remove the filler plug from the filler orifice.

D.2.2 Pour the anaesthetic agent into the filler as described in the user instruction manual until the liquid overflows.

D.2.3 Wait until overflowing of liquid has ceased and replace the filler plug.

D.3 Fillers where the vaporizer is directly connected to the bottle of anaesthetic agent (agent-specific filling system)

D.3.1 Take a bottle of anaesthetic agent sufficient to fill the vaporizer.

D.3.2 Fill the vaporizer with anaesthetic agent as described in the user instruction manual until the flow of liquid ceases.

D.3.3 Disconnect the filling apparatus, if removable, and allow any excess liquid to drain. Close the filling ports.

Annex E
(informative)

Bibliography

[1] BS 5252:1976, *Framework for colour co-ordination for building purposes.*

[2] DIN 6164-2:1980, *DIN colour chart — Part 2: Specification of colour samples.*

[3] USA Federal Standard 595a, *Colors* — Volume 1.[1)]

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[5] Pantone Colours.[3)]

[6] SS 01 91 00, *Colour notation system.*

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1) Available from Superintendant of Documents, US Government Printing Office, Washington DC 20402, USA.
2) Available from Munsell Color, 2441 N. Calvert Street, Baltimore, Maryland 21218, USA.
3) Available from Letraset UK Ltd., 195 Waterloo Road, London SE1, United Kingdom.

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